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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,785	04/20/2001	Ted Lau	51831AUSM1	9790

7590 05/07/2002

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EXAMINER	
DAVIS, MINH TAM B	
ART UNIT	**PAPER NUMBER**
1642	6

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/838,785	LAU ET AL	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-7, 10-12, drawn to a polynucleotide encoding SEQ ID No:2, a polynucleotide of SEQ ID NO:1, and fragments thereof, classified in class 536, subclass 23.1.

Group II. Claims 8, 38, drawn to a vector comprising a polynucleotide encoding SEQ ID No:2, a polynucleotide of SEQ ID NO:1, and fragments thereof, and a vaccine comprising said vector for *in vivo* administration and immunizing a human against prostate cancer, classified in class 435, subclass 320.1.

Group III. Claim 9, drawn to a host cell comprising a vector comprising a polynucleotide encoding SEQ ID No:2, a polynucleotide of SEQ ID NO:1, and fragments thereof, classified in class 435, subclass 325.

Group IV. Claim 13, drawn to a method for producing a cell which expresses a polypeptide comprising engineering the cell with a vector comprising a polynucleotide encoding SEQ ID No:2, a polynucleotide of SEQ ID NO:1, and fragments thereof, classified in class 435, subclass 252.3.

Group V. Claims 14-15, 37, drawn to a polypeptide of SEQ ID NO:2, fragments and variants thereof, classified in class 530, subclass 350.

Groups VI-X. Claims 16-27, drawn to an antibody or an immunoconjugate that specifically binds to 1) SEQ ID NO:2 and SEQ ID NO:23, 2) SEQ ID NO:2 and

SEQ ID NO:26, 3) SEQ ID NO:2 and SEQ ID NO:25, 4) SEQ ID NO:2 and SEQ ID NO:21, and 5) SEQ ID NO:2 and SEQ ID NO:24, classified in class 530, subclass 387.1. The claims 16-27 would be examined as drawn to the elected one of the five groups. Applicant must identify the group to which each of claims 17-21 belongs. In addition, upon election of one of said groups, Applicant must elect a single sequence species for examination.

Groups XI-XV. Claims 28-29, drawn to a method for selectively killing a cell or treating a disease-state associated with inappropriate expression of PROST3, comprising administering an immunoconjugate that selectively binds to 1) SEQ ID NO:2 and SEQ ID NO:23, 2) SEQ ID NO:2 and SEQ ID NO:26, 3) SEQ ID NO:2 and SEQ ID NO:25, 4) SEQ ID NO:2 and SEQ ID NO:21, and 5) SEQ ID NO:2 and SEQ ID NO:24, classified in class 424, subclass 130.1. The claims 28-29 would be examined as drawn to the elected one of the five groups. In addition, upon election of one of said groups, Applicant must elect a single sequence species for examination.

Group XVI. Claim 30, drawn to a method for treating a disease-state associated with inappropriate expression of PROST3, comprising administering SEQ ID NO:2, classified in class 514, subclass 2.

Group XVII. Claim 31, drawn to a method for treating a disease-state associated with inappropriate expression of PROST3, comprising administering a polynucleotide encoding SEQ ID NO:2, or a portion thereof, classified in class 514, subclass 44.

Group XVIII- XXII. Claims 32-33, drawn to a method for diagnosing the presence of a polypeptide, using an antibody that specifically binds to 1) SEQ ID NO:2 and SEQ ID NO:23, 2) SEQ ID NO:2 and SEQ ID NO:26, 3) SEQ ID NO:2 and SEQ ID NO:25, 4) SEQ ID NO:2 and SEQ ID NO:21, and 5) SEQ ID NO:2 and SEQ ID NO:24, classified in class 435, subclass 7.1. The claims 32-33 would be examined as drawn to the elected one of the five groups. In addition, upon election of one of said groups, Applicant must elect a single sequence species for examination.

Group XXIII. Claim 34, drawn to a method for diagnosing the presence of a polynucleotide, classified in class 435, subclass 6.

Group XXIV-XXVIII. Claims 35-36, drawn to a method for diagnosing metastasis, using an antibody that specifically binds to 1) SEQ ID NO:2 and SEQ ID NO:23, 2) SEQ ID NO:2 and SEQ ID NO:26, 3) SEQ ID NO:2 and SEQ ID NO:25, 4) SEQ ID NO:2 and SEQ ID NO:21, and 5) SEQ ID NO:2 and SEQ ID NO:24, classified in class 435, subclass 7.1. The claims 35-36 would be examined as drawn to the elected one of the five groups. In addition, upon election of one of said groups, Applicant must elect a single sequence species for examination.

In addition, upon election of any of groups VI-X, further election of the following species is required:

Antibody or immunoconjugate.

Antibodies or immunoconjugates to full length or fragments of SEQ ID NO:2.

Upon election of immunoconjugate, further election of the following species is required:

Any one of the cytotoxic agent recited in claim 26.

Upon election of any of groups XI-XV, further election of the following species is required:

Any one of the cytotoxic agent recited in claim 26.

The inventions are distinct, each from each other because of the following reasons:

Inventions (I-III, V-X) and (IV, XI-XXVIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases; a vector could be used for making an expression vector, for expressing a protein or for killing a host cell; and a host cell could be used for testing drugs, for expression of a transgene, or *for in vivo* delivering to a patient..

The products of groups (I-III, V-X) are patentably distinct, because they are drawn to entirely different biochemicals , having different structures, biological

properties and activities that are not interchangeable and cannot be used in place of each other.

The methods of groups (IV, XI-XXVIII) are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species antibody or immunoconjugate are distinct because they are structurally distinct.

The species cytotoxic agents are distinct because they are structurally distinct.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

April 22, 2002